

Appln No. 10/552,483

Amdt date January 6, 2010

Reply to Office action of October 6, 2009

REMARKS/ARGUMENTS

As a preliminary matter, Applicant acknowledges the Examiner's statement regarding the recitation of a strain deposited under accession number NCIM 41171. If Applicant becomes aware of any change regarding the status of this deposit, Applicant will disclose any relevant information to the office.

With this amendment, claims 1, 4, 6, 9-13, 16-21, and 22-27 are pending. Claims 1, 6, 9-13, 16-19 and 21 are amended, claims 2, 3, 5, 7-8 and 14-15 are cancelled without prejudice, and claims 22-25 are new. Amendments to the claims find full support in the original specification, claims and drawings, and for example, at page 5, lines 25-27. New claims 22-27 find full support in the original application and, for example, at page 8, lines 4-14 and Example 7, pages 25-26. No new matter is presented. Applicant submits that the objections to claims 5 and 15-21 for informalities have been remedied by the amendments made herein.

In the Office Action of October 6, 2009, claims 3, 4, and 15 are rejected under 35 U.S.C. 112, first paragraph for allegedly lacking enablement. Claims 3 and 15 are cancelled. Independent claim 1 has been amended as shown herein and now recites the disclosed strain NCIMB 41171 from *Bifidobacterium bifidum*. Claim 4 depends from claim 1 and the further limitations are supported at page 5, lines 25-27. Accordingly, independent claim 1 and all pending claims are enabled by the specification.

Claims 2-5, 7-13, 15-17, and 21 are rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite. In view of the cancellation of claims 2-3, 5, 7-8 and 14-15 and the amendment of claims 1, 6, 9-13, 16-19 and 21 as shown herein, Applicant submits that all pending claims particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

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Claims 12, 13, and 16-17 are rejected under 35 U.S.C. 101 for reciting a use without setting forth any steps in the process. Applicant has amended claims 12, 13, and 16-17 to recite steps in accordance with 35 U.S.C. 101.

Claims 1, 2, 5-7, 10, 11, and 14 are rejected under 35 U.S.C. 102(b) as allegedly anticipated by Dumortier et al. (Carbohydrate Research, 1990, 201:115-123). Specifically, the Examiner alleges that Dumortier discloses a lactose solution incubated with a cell suspension of *Bifidobacterium bifidum* DSM 20456 resulting in the formation of 10 galactooligosaccharides, and thereby anticipates the recited invention. However, as amended herein, independent claims 1 and 6, recite *a galactooligosaccharide . . . comprising disaccharide Gal (α1-6)-Gal, at least one trisaccharide selected from the group consisting of Gal (β1-6)-Gal(β1-4)-Glc and Gal (β1-3)-Gal (β1-4)-Glc, tetrasaccharide Gal (β1-6)-Gal(β1-6)-Gal(β1-4)-Glc and pentasaccharide Gal (β1-6)-Gal(β1-6)-Gal (β1-6)-Gal(β1-4)-Glc*. The claimed mixture of galactooligosaccharides is not disclosed by Dumortier, nor is the claimed mixture possible using the galactosidase of Dumortier because as disclosed throughout and on page 21, the β-D-galactoside galactohydrolase enzyme produces only β linkages. As such, the enzyme of Dumortier as disclosed, does not and could not produce the recited α1-6 linkage of the disaccharide in independent claims 1 and 6. Accordingly, independent claims 1 and 6, and all claims depending therefrom, including claims 2, 10, and 11, are not anticipated by Dumortier.

Claims 6 and 9 are rejected under 35 U.S.C. 102(e) as allegedly anticipated by Gibson et al. (US 2004/0131659). Applicant respectfully disagrees. As discussed above, amended independent claims 1 and 6 recite, *a galactooligosaccharide composition. . . comprising disaccharide Gal (α1-6)-Gal, at least one trisaccharide selected from the group consisting of Gal (β1-6)-Gal(β1-4)-Glc and Gal (β1-3)-Gal (β1-4)-Glc, tetrasaccharide Gal (β1-6)-Gal(β1-6)-Gal(β1-4)-Glc and pentasaccharide Gal (β1-6)-Gal(β1-6)-Gal (β1-6)-Gal(β1-4)-Glc*. The claimed galactooligosaccharide composition of independent claims 1 and 6, is not disclosed by Gibson. MPEP § 2131.02 states that a generic chemical formula will anticipate a claimed

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species covered by the formula when the species can be "at once envisaged" from the formula. When the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, *e.g.*, select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be "at once envisaged."

While Gibson appears to disclose galactooligosaccharide (GOS) units of varying amounts and by varying weight percents at paragraph [0027], Gibson, does not disclose the recited saccharides of independent claim 6. One of ordinary skill in the art considering Gibson, and specifically paragraph [0027], would not envisage the recited *disaccharide Gal (α1-6)-Gal, at least one trisaccharide selected from the group consisting of Gal (β1-6)-Gal(β1-4)-Glc and Gal (β1-3)-Gal (β1-4)-Glc, tetrasaccharide Gal (β1-6)-Gal(β1-6)-Gal(β1-4)-Glc and pentasaccharide Gal (β1-6)-Gal(β1-6)-Gal (β1-6)-Gal(β1-4)-Glc*. Accordingly, independent claims 1 and 6, and all claims depending therefrom, including claim 9, are not anticipated by Gibson.

Claims 1, 2, 5-7, 10-14, and 16-21 are rejected under 35 U.S.C. 103(a) as allegedly obvious over Dumortier in view of Jorgensen et al. (US 2002/0086358), Ziggers (Feed Mix, 2001, 9(6): 7-9, and De Jong et al. (WO 00/33854). Applicant respectfully disagrees. As discussed above, nothing in Dumortier suggests or contemplates the recited galactooligosaccharide mixtures of claims 1 and 6. As discussed above, the galactooligosaccharides of Dumortier have only β linkages, as the enzyme of Dumortier does not produce an oligosaccharide having an α 1-6 linkage. With respect to Joegensen, Ziggers and De Jong, these references teach various oligosaccharides and bacterial strains for use in gut health. However, none of these references teach or suggest the recited galactoolisaccharide mixtures of

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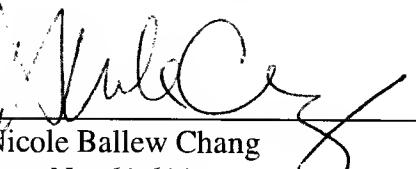
claims 1 and 6. As such, taken independently or in combination, the cited references fail to render claims 1 and 6 obvious. Accordingly, independent claims 1 and 6, and all claims depending therefrom, including claims 2, 6, 10-13 and 16-21 are allowable over Dumortier in view of Jorgensen, Ziggers and De Jong.

With this response, new claims 22-25 are added, each of which depends indirectly from independent claim 6. For reasons discussed above for claim 6, new claims 22-25 are also allowable over the cited art.

In view of the above amendments and remarks, Applicant submits that all of pending claims 1, 4, 6, 9-13, 16-21, and 22-27 are in condition for allowance. Applicant therefore respectfully requests a timely indication of allowance. However, if there are any remaining issues that can be addressed by telephone, applicant invites the examiner to contact applicant's counsel at the number indicated below.

Respectfully submitted,
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